

Pilot, Double-Blind, Placebo-Controlled, Parallel Group Study of the Safety and Clinical Activity of CCX282-B in Patients with Moderate to Severe Crohn's Disease

Submission date 13/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/01/2021	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00102921

Protocol serial number

CL003_282_b

Study information

Scientific Title

Pilot, Double-Blind, Placebo-Controlled, Parallel Group Study of the Safety and Clinical Activity of CCX282-B in Patients with Moderate to Severe Crohn's Disease

Acronym

CCX

Study objectives

The purpose of this research study is to investigate the effects of an investigational medication, called CCX282-B, on safety and on some of the symptoms of Crohn's Disease in patients who are experiencing an active flare-up of moderate to severe Crohn's Disease

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Crohn's Disease

Interventions

An investigational medication, called CCX282-B (capsules), compared to placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

CCX282-B

Primary outcome(s)

The primary immunologic and clinical activity objective of this study is to provide pilot information regarding the immunologic and clinical activity of daily oral doses of CCX282-B in the treatment of moderate to severe Crohn's Disease, based on changes in the Crohn's Disease Activity Index (CDAI).

Key secondary outcome(s)

Secondary immunologic and clinical activity objectives include evaluation of the effect of CCX282-B on the Inflammatory Bowel Disease Questionnaire (IBDQ) instrument, C-reactive protein (CRP), the endoscopic appearance and biopsy of the colon and terminal ileum, and markers of leukocyte subsets and activation status.

Completion date

01/02/2006

Eligibility**Key inclusion criteria**

1. Diagnosis of moderate to severe Crohn's Disease in small intestine; disease must be active at the time of study entry
2. Use of adequate and approved methods of birth control throughout the study period
3. Willing and able to sign an informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Pregnant or breastfeeding
2. Infection with hepatitis B, hepatitis C, or human immunodeficiency virus (HIV; the virus that causes AIDS)
3. Abuse of alcohol or of illegal drugs

Date of first enrolment

01/08/2004

Date of final enrolment

01/02/2006

Locations**Countries of recruitment**

Netherlands

Study participating centre

Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
ChemoCentryx (USA)

ROR
<https://ror.org/04gp12571>

Funder(s)

Funder type
Industry

Funder Name
ChemoCentryx

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration